

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

BEER ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2004/003736

FiLED: 7 APRIL 2004

U.S. APPLICATION NO: 10/551,107

35 USC §371 DATE: 26 SEPTEMBER 2005

FOR: SYNBIOTIC COMBINATION

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

# COMMUNICATION IN RESPONSE TO THE NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. § 371

Sir:

On February 23, 2006, the USPTO issued the Notification of Missing Requirements Under 35 U.S.C. § 371, a copy of which is enclosed.

The undersigned submitted the executed Declaration to the USPTO on January 5, 2006 in a Second or Subsequent Submission of Items Concerning a Filing Under 35 U.S.C. § 371. Enclosed please find a copy this Second or Subsequent Submission, a copy of the executed Declaration.

Because Applicants submitted the executed Declaration on January 5, 2006 with authorization to charge the \$130.00 late fee and any additional fees to our deposit account, no fee is required.

Respectfully submitted,

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-7954

Date: 20 March 2006

Gary M. Løbel

Attorney for Applicants Reg. No. 51,155

| Form PTO-1390-MOD<br>(REV 10-96)  |   |  | Department of Commerce Patent and Trademark Office   | ATTORNEY'S DOCKET NUMBER N-33151A               |  |  |  |  |  |  |
|---|---|--|--|---|--|--|--|--|--|--|
| ,   |   | TRANSMITTAL LETTER TO T  | HE UNITED STATES   | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) |  |  |  |  |  |  |
|   |   | DESIGNATED/ELECTED O   |  | 10/551,107                                      |  |  |  |  |  |  |
|   | CONCERNING A FILING UNDER 35 U.S.C. 371 |  |  |   |  |  |  |  |  |  |
| ĪNī   | ERI                                     | NATIONAL APPLICATION NO.   | INTERNATIONAL FILING DATE  | PRIORITY DATE CLAIMED                           |  |  |  |  |  |  |
|   |   | P2004/003736   | 7 April 2004 (07.04.04)  | 8 April 2003 (08.04.03)                         |  |  |  |  |  |  |
| TIT   | TITLE OF INVENTION                      |  |  |   |  |  |  |  |  |  |
| SYNBIOTIC COMBINATION  APPLICANT(S) FOR DO/EO/US  |   |  |  |   |  |  |  |  |  |  |
| BEER ET AL.   |   |  |  |   |  |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: |   |  |  |   |  |  |  |  |  |  |
| 1.  | П                                       | This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.   |  |   |  |  |  |  |  |  |
| 2.  | Ø                                       | This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.  |  |   |  |  |  |  |  |  |
| 3.  | Ш                                       | examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).   |  |   |  |  |  |  |  |  |
| 4.  |   | A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority  |  |   |  |  |  |  |  |  |
| 5.  |   | date.  A copy of the International Application as filed (35 U.S.C. 371(c)(2))  a.   is transmitted herewith (required only if not transmitted by the International Bureau).  |  |   |  |  |  |  |  |  |
|   |   | nai Bureau).<br>08)  |  |   |  |  |  |  |  |  |
|   |   | c. is not required, as the application   | mational Bureau. (See Form PCT/IB/30 was filed in the United States Receiving the Control of the | ng Office (RO/US).                              |  |  |  |  |  |  |
| 6.<br>7.  | $\exists$                               | A translation of the International Application into English (35 U.S.C. 371(c)(2)).  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C.371(c)(3)).   |  |   |  |  |  |  |  |  |
| ٠.  |   | a. are transmitted herewith (required b. have been transmitted by the International Control of the Inte | d only if not transmitted by the Internati   | nsmitted by the International Bureau).          |  |  |  |  |  |  |
|   |   | nts has NOT expired.   |  |   |  |  |  |  |  |  |
|   | _                                       | c. have not been made; however, the time limit for making such amendments has NOT expired. d. have not been made and will not be made.   |  |   |  |  |  |  |  |  |
| 8.<br>9.  | $\mathbb{A}$                            | A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).  An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).  |  |   |  |  |  |  |  |  |
| -   | Ö                                       | A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C.   |  |   |  |  |  |  |  |  |
|   | 371(c)(5)).                             |  |  |   |  |  |  |  |  |  |
| Items 11. to 16. below concern document(s) or information included.   |   |  |  |   |  |  |  |  |  |  |
| 11.   |   | An Information Disclosure Statement under 37 CFR 1.97 and 1.98.  |  |   |  |  |  |  |  |  |
| 12.   |   | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.  |  |   |  |  |  |  |  |  |
| 13.   |   | A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment.   |  |   |  |  |  |  |  |  |
| 14.   |   | An Application Data Sheet under 37 CFR 1.76.   |  |   |  |  |  |  |  |  |
| 15.   |   | A substitute specification.  |  |   |  |  |  |  |  |  |
| 16.   |   | A change of power of attorney and/or address letter.   |  |   |  |  |  |  |  |  |
| 17.   |   | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.   |  |   |  |  |  |  |  |  |
| 18.   |   | A second copy of the published International Application under 35 U.S.C. 154(d)(4).  |  |   |  |  |  |  |  |  |
| 19.   |   | A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).  |  |   |  |  |  |  |  |  |
| 20.   |   | Other items or information:  |  |   |  |  |  |  |  |  |

BEST AVAILABLE COPY

| U.S. APPLICATION NO.   | if known, see   | 37 CFR 1.5)                 | INT                  | ERNATIONAL APPLICATION N<br>CT/EP2004/003736           | NO.             |                    | 1                 | TORNEY'S DO<br>N-33151A | CKET NUI        | WBER                  |              |
|--|---|-----------------------------|----------------------|--|-----------------|--------------------|-------------------|-------------------------|-----------------|-----------------------|--------------|
| 10/551,107   |   |                             |                      | rC1/E12004/003723                                      |                 |                    |                   | CALCULATIONS PTO USE    |                 |                       |              |
| The following fee  | s are sul   | omittea:                    |                      |  |                 |                    |                   |                         | ONLY            |                       |              |
|  |   | _                           |                      |  |                 |                    |                   | \$                      |                 |                       | ļ            |
| 21. Basic national fee   |   |                             |                      |  |                 |                    |                   |                         |                 | i i                   |              |
| 22. Examination  | 22. Examination Fee  If International preliminary examination report was prepared by USPTO  \$ 100.0000000000000000000000000000000000   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| If Inte  | mational  | preliminar<br>eatisfy pro   | y examinations of Po | CT Article 33(1)-(4)                                   |                 |                    |                   | \$                      |                 |                       | 1            |
| If International preliminary examination report was proposed by and all claims satisfy provisions of PCT Article 33(1)-(4)   |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| All other situations   |   |                             |                      |  |                 |                    |                   |                         | l l             |                       |              |
| ·  |   |                             |                      |  |                 |                    |                   |                         |                 | Ì                     |              |
| 23. Search fee   | and foo   | 37 CFR 1.                   | 445(a)(2)) h         | as been paid on the i                                  | internation     | nal                |                   | _                       | •               |                       |              |
| 23. Search fee  If Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority   |   |                             |                      |  |                 |                    |                   | l I                     |                 |                       |              |
|  | 4°  | I CASTON H                  | onon was n           | repared and provided                                   | , 10 1110 0     |                    | -                 | \$                      |                 |                       | Ì            |
| - All ot   | her situa   | tions                       |                      |  |                 |                    |                   |                         | -               |                       |              |
|  |   |                             | TOTAL                | OF 21, 22 AND 23 =                                     |                 |                    |                   |                         | \$              | 0                     |              |
|  | if-   | ation and o                 |                      | 400 -  | -banta (a)      | cludir             | ng sequ           | ence listing            | or com          | puter                 |              |
| Additional fee to  | r specific<br>iled in ar  | electronic                  | medium).             | d in paper over 100 s<br>he fee is <b>\$250</b> for ea | ach additi      | onal 5             | 0 sheet           | s of paper of           | or fractio      | on                    |              |
| thereof  |   |                             |                      | each additional 50 o                                   |                 | $\neg$             |                   | ATE                     | T               |                       |              |
| Total Sheets   | Extra   | sheets                      | thereof (ro          | und up to a whole nu                                   | ımber)          |                    |                   |                         | 1               |                       |              |
| - 100 =  |   | /50 =                       |                      |  |                 | X                  | \$                | 250                     | <del>  \$</del> |                       |              |
|  |   |                             | and the of doe       | laration later than                                    | ⊠ 30            |                    |                   |                         | s               | 130                   |              |
| Surcharge of \$1   | 30 for tu   | claimed pri                 | iority date (3       | laration later than<br>7 CFR 1.492(e)).                |                 |                    |                   | _                       |                 |                       |              |
| CLAIMS   | Earlicot  | NUMB                        | EK FILED             | NOMBERT  | TRA             | X                  | RAT<br>\$         | 50                      | \$              |                       |              |
| Total claims   |   |                             | - 20<br>- 3          |  |                 | $\hat{\mathbf{x}}$ | \$                | 200                     | \$              |                       |              |
| independent cla  | ims<br>ENDEN  | T CLAIM(S                   |                      | امار)  |                 | +                  | \$                | 360                     | \$              | 100                   |              |
|  |   |                             |                      |  |                 |                    |                   | =   \$                  | 130             |                       |              |
| Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be   |   |                             |                      |  |                 |                    |                   | <b>S</b>                |                 |                       |              |
| filed (Note 37 CFR 1.9, 1.27, 1.26).   |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
|  | to a \$ \$4.20 for furnishing the English translation later than 30 months from the   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| earliest claimed   | priority  | date (37 CF                 | R 1.492(f)).         |  |                 |                    |                   |                         | \$<br>=   \$    | 130                   |              |
| earliest claimed priority date (37 CFR 1.492(f)).  TOTAL NATIONAL FEE =  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied  + 1.21(h) + 1.21( |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| Fee for recording  | ng the en   | closed assi                 | gnment (37           | CFR 1.21(h)). The a                                    | assignine<br>ty | ant mu             | ist be at         | +                       | \$              |                       |              |
| Fee for recording the enclosed assignment (37 OFR 3.28, 3.31). \$40 per property  by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property  TOTAL FEES ENCLOSED  |   |                             |                      |  |                 |                    |                   | = ] \$                  | 130             |                       |              |
|  |   |                             |                      |  |                 |                    |                   | •                       |                 | Amount to             | \$           |
|  |   |                             |                      |  |                 |                    |                   |                         | be              | : refunded<br>charged | \$           |
|  |   |                             |                      |  |                 |                    |                   | <del></del>             |                 | Onargou               | <u> </u>     |
| a. A che   | a. A check in the amount of \$ to cover the above fees is enclosed.   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| Places charge Denosit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above tees. A  |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| The state of this form is enclosed.  |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| c. 🛛 The C   | c.   The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis. |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| Depos  | SIT ACCOU   | IIL 140. 1 <del>3-</del> 0  | , 5-, 11, 410 11     |  |                 | _                  |                   |                         | lion to :       | rovive (27            | CED 1 127/a\ |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.  |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| or (b)) must b   | e filed ar  | nd granted                  | fo tezroie           | the application to P                                   |                 |                    |                   |                         | /               |                       |              |
| Send all correspondence to the address associated with   |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
| Customer No. 001095, which is currently.   |   |                             |                      |  |                 |                    |                   |                         |                 |                       |              |
|  |   |                             |                      |  | Gar             | y M/L              | obel              | licanta                 |                 |                       |              |
| Novart   | is  |                             |                      |  |                 |                    | for App<br>51,155 |                         |                 | •                     |              |
| Corpor   | rate Intell   | ectual Prop<br>za, Building | eπy<br>104           |  | (86             | 2) 778             | 3-7954            |                         |                 |                       |              |
| East H   | ianover, l  | J 07936-1                   | 080                  |  |                 |                    |                   |                         |                 |                       |              |



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandra, Vriginia 22313-1450 www.napto.gov

INTERNATIONAL APPLICATION NO.

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/551,107

Michael Beer

N-33151A

PCT/EP04/03736

I.A. FILING DATE

PRIORITY DATE

04/07/2004

04/08/2003

1095 **NOVARTIS** CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 **EAST HANOVER, NJ 07936-1080** 

**CONFIRMATION NO. 4371 371 FORMALITIES LETTER** OC000000018053121

Date Mailed: 02/23/2006

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 09/26/2005
- Copy of the International Search Report filed on 09/26/2005
- Preliminary Amendments filed on 09/26/2005
- Information Disclosure Statements filed on 09/26/2005
- Oath or Declaration filed on 09/26/2005
- U.S. Basic National Fees filed on 09/26/2005
- Priority Documents filed on 09/26/2005
- Specification filed on 09/26/2005
- Claims filed on 09/26/2005
- Abstracts filed on 09/26/2005
- Drawings filed on 09/26/2005



The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - 1ST Inventor Signature Missing

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

DOCKETED FOR:

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

#### PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

## PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/551,107                  | PCT/EP04/03736                | N-33151A         |

FORM PCT/DO/EO/905 (371 Formalities Notice)